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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,473

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Barry M. Tydings

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EXAMINER

SIEFKE, SAMUEL P

ART UNIT

PAPER NUMBER

1797

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/826,473	TYDINGS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SAM P. SIEFKE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 67-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

Claims 67-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation requiring the flow path for a urine sample to “solely wick up the wicking” to be terminated upon reaching the assay strip and to provide continuous flow to the assay strip introduced new matter which is not described or supported in the specification. From the instant specification (page 5, line 16, “As soon as the urine sample is introduced, the cap 4 should be tightly screwed onto the container 2 to prevent any contamination of the urine sample. **The urine then wicks up the wicking material 10 until it reaches the overlapped portions of the assay strips 12. The urine then wicks over the top edge of the backing 8 and down the assay strips 12. The urine wicking down the assay strips 12 will react with the chemical agents contained therein and will give positive, negative or inconclusive test results.**” Claim 67 does not remotely claim this flow of urine in the device. The Applicant is trying to incorporate limitations into the claims that are nowhere to be found in the instant specification. Claim 67 states, “the urine wicks solely up the wick portion until it reaches an overlapped portion of the wicking portion and the first portion of the assay strip and thereafter flows upwards in the first portion of the

Art Unit: 1797

assay strip, wherein in use the action of the urine wicking solely upwardly along the wicking portion in an upward direction in the container from the base towards the top, and thereafter flows upwards in the first portion of the assay strip. Further, "components including a first portion of an assay strip and a wicking portion" is not recited in the specification that allows the wording to be employed in the claims.

Claims 67-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation of "solely wick up the wicking" is ambiguous in scope because it cannot discern what the limitation intends. For example, does the term "solely" require that the fluid flow be provided exclusively by the wicking member or alternatively that the flow is conducted exclusively in an upward direction?

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 67-75 are rejected under 35 U.S.C. 102(b) as being anticipated by MacKay et al. (USPN 5,656,502).

MacKay discloses a test strip holder that is placed into a container that holds a sample to be tested. A test strip is disposed in a holder having a backing having a front surface (fig. 5, ref. 26) and is in liquid transmittable contact with a wicking (35, col. 7, lines 19-24), the wicking has a lower portion proximal to the base of the container (Fig. 3a), the urine wicks solely up the wick until it reaches the assay strip, the container is in an upright position (fig 3a), a front cover (fig. 4 ref. 22) provided on the front surface of the backing for locating the assay strip to the backing, the backing together with the front cover and the assay strip being located adjacent a wall of the container and extending from a position proximal to the top of the container to a position proximal to the bottom of the container so that in use the action of the urine consists of wicking solely upwardly along the wicking in the container from the base toward the top.

Claims 67-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Klimov et al. (USPN 5,770,458).

Klimov discloses an assaying device and method for in field analysis of a specimen. The assembly comprises: a partially transparent container (1a) having a opening for collecting a urine sample (fig. 1a, 1b); a wall (110, liquid impermeable); a cover for sealing the container (col. 10, lines 47-51); an assay assembly having at least one assay strip (101) being in liquid transmittable contact with a wicking material (109), the wicking material being in communication with the urine (when the urine is filled to over flow into the collection portion in fig. 1b, the upper top above wicking 109); the

Art Unit: 1797

assay strip being directed adjacent to the wall of the container thereby being readable through the container wall (fig. 1, cover 48 is transparent ,col. 10, lines 53-57); the assay strips are separated by longitudinal slots; (fig. 1a); a transverse slot for accommodating the end of the test strips (fig. 1a bottom of test strips); a series of assay strips in parallel relationship (fig. 1a); assay strip is substantially the same height of the container (fig. 1a); the assay assembly conforms to the inner wall of the container (fig. 1a.); a screw on cap (not shown but has option for screw on cap and is disclosed fig. 1a col. 10, lines 47-51).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 21-30 of U.S. Patent No. 6,805,837. The presently pending claims 58-66 are a broader version of Patent No. 6,805,837. 6,805,837 claims include all the limitations found in the presently pending claims. Thus, the presently pending claims cover all the subject matter of 6,805,837.

Claims 67-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,379,620. The presently pending claims 58-66 are a broader version of Patent No. 6,379,620. 6,379,620 claims include all the limitations found in the presently pending claims. Thus, the presently pending claims cover all the subject matter of 6,379,620.

Claims 67-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,805,838. The presently pending claims 58-66 are a broader version of Patent No. 6,805,838. 6,805,838 claims include all the limitations found in the presently pending claims. Thus, the presently pending claims cover all the subject matter of 6,805,838.

Claims 67-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,730,268. The presently pending claims 58-66 are a broader version of Patent No. 6,730,268. 6,730,268 claims include all the limitations found in the presently pending claims. Thus, the presently pending claims cover all the subject matter of 6,730,268.

***Response to Arguments***

Applicant's arguments filed 8/6/08 have been fully considered but they are not persuasive. The Applicant has not discussed the 112 new matter rejection or removed the claimed subject matter from the claims the Examiner recognized as new matter.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.



Art Unit: 1797

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/  
Primary Examiner, Art Unit 1797